NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

April 4, 2000

Jane Henney, MD
Commissioner of Food and Drugs
(HF-1)
Room 1471
5600 Fishers Lane
Rockville MD 20857

RE: [Docket No. 94P-0390 and 95P-0241] Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims.
60 Federal Register 66206, December 21, 1995

[Docket Nos. 91N-0101, 91N-0098, 91N-0103, and 91N-100H] Food Labeling: Health Claims and Label Statements for Dietary Supplements; Strategy for Implementation of *Pearson* Court Decision
64 Federal Register 67289, December 1, 1999

Dear Dr. Henney:

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5900

I am writing to you, on behalf of the National Food Processors Association (NFPA), to object to FDA's announced strategy for implementing the landmark First Amendment decision in *Pearson v. Shalala.*

NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA's members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks, and juices, or provide supplies and services to food manufacturers.

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FDA's strategy for implementing the *Pearson v. Shalala* decision excludes conventional foods, even though the violative FDA policy addressed in *Pearson* applies squarely to conventional foods. FDA's strategic decision is particularly disappointing since there is a pending FDA rulemaking on conventional food health claims which was initiated specifically in response to a 1994 NFPA Citizen Petition

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(Docket No. 94P-0390) seeking health claim policy reforms on the same First Amendment grounds now required by the court in *Pearson*.

FDA's Center for Food Safety and Applied Nutrition (CFSAN) has announced, as part of its Year 2000 Priorities, that it intends to publish a final rule related to issues raised in our 1994 petition – an action which we urged the Agency to take. However, NFPA believes strongly that proceeding to the publication of this final rule without consideration of the issues addressed in the *Pearson* decision would be arbitrary and capricious.

FDA's announced strategy to implement the *Pearson* decision improperly treats the holding of that case as though it applies only to dietary supplements. The basic First Amendment concerns expressed by the *Pearson* court did not turn on the fact that the health claims defects at issue were raised by dietary supplement marketers. Three of the four health claims sub-regulations invalidated by the court (21 CFR §101.71(a), (c), and (e)), as well as FDA's interpretation of its general regulation (21 CFR §101.14) apply equally to dietary supplements and conventional foods. The *Pearson* court explicitly noted that FDA regulates health claims for dietary supplements and conventional foods using the same substantive standard for authorization and procedure for evaluating a claim's validity. *Pearson*, 164 F.3d at 653 note 2.

As noted in the *Pearson* decision, the actual First Amendment violation arose directly from FDA's policy under the "significant scientific agreement" standard, which FDA applies to conventional foods and dietary supplements alike. We see no way that FDA can remedy the First Amendment violation found in *Pearson*, while limiting its consideration to dietary supplement health claims - and yet this is precisely what FDA has said it will do.

This approach is plainly inconsistent with FDA's long-standing policy and practice of regulating health claims for conventional foods and dietary supplements identically. In the preamble to FDA's final rule on health claims for dietary supplements, the Agency stated that "applying the same standard and procedure to health claims on dietary supplements as that that applies to foods in conventional food form... will subject all segments of the food industry to regulation in a fair and consistent manner" (59 FR 395, at 403; January 4, 1994). This is a position the government continued to take in District Court argument in the *Pearson* case. *Pearson v. Shalala*, 14 F. Supp. 2d 10 (D.C. District Court 1998).

The *Pearson* implementation strategy announced by FDA on December 1, 1999 makes no reference to policy reforms that would reach conventional foods, but

rather characterizes its planned "rulemaking to reconsider the general health claim regulations" as focusing only on "dietary supplements" (64 FR 67289; December 1, 1999) (emphasis added).

We could not disagree more strongly with FDA's approach for *Pearson* implementation. Beyond the First Amendment problems, the strategy evidences an intent by FDA to develop divergent health claim policies for conventional foods and dietary supplements, delaying full reforms for conventional foods. This delay is unacceptable, especially since our petition seeking *Pearson*-type reforms has been pending now for over five years. We urge FDA to take steps promptly to ensure equal treatment of conventional foods and dietary supplements under *Pearson*.

Our comments filed on the Year 2000 Program Priorities in the Center for Food Safety and Applied Nutrition (Docket No. 98N-0359; 64 FR 47845) on September 30, 1999 made the same point.

> "NFPA believes that ... CFSAN should concentrate effort on related subjects dealing with expression of health claims and nutrient content claims on food labels. Working on several related subjects simultaneously can take advantage of critical intellectual mass, and will ensure greater consistency in outcome of these policy topics. As many of these subjects will necessitate new thinking because of the court decision in *Pearson v. Shalala*, NFPA feels it is timely to link these projects to the development of an implementation strategy for *Pearson*, which is a CFSAN mid-term 1999 goal in the dietary supplements program. In the same vein, NFPA believes that work assigned to the "B" list in 1999 should be subject to elevation to the "A" list in 2000. Consequently, NFPA recommends that FDA assign all the following subjects to the "A" priority list for the Nutrition, Health Claims and Labeling program:
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> 1. In response to citizen petitions 94P-0390 [NFPA petition] and 95P-0241, publish a final rule amending the regulations on nutrient content claims and health claims to provide additional flexibility in the use of these claims on food products." [emphasis added]

Our intention with this comment was to advise FDA of its responsibility to implement general reforms required under the *Pearson* decision with respect to health claims policies for conventional foods, and to do so promptly in the context of the Agency's rulemaking in response to the 1994 NFPA Citizen Petition. We must emphasize, however, that we would object to FDA publishing a final rule without providing for full consideration of the First Amendment

issues in the context of the pending rulemaking. These issues no longer can be ignored by FDA under *Pearson*.

NFPA believes most strongly that the *Pearson* decision applies to health claims for conventional food. To implement the *Pearson* decision fully, FDA must ensure that the policy reforms needed to protect truthful, nonmisleading health claims from unconstitutional regulation extend equally to both conventional foods and dietary supplements.

Consequently, NFPA urges FDA to implement the *Pearson* decision for conventional foods in the same manner and on the same schedule as for dietary supplements.

Best regards,

John Cady

John R. Cady
President and Chief Executive Officer

cc: Dockets Management Branch, FDA
Joseph Levitt, CFSAN-FDA
Christine Lewis, Ph.D., CFSAN-FDA